Message

From: Beck, Nancy [Beck.Nancy@epa.gov]
Sent: 5/11/2018 10:01:18 PM
To: Anastasia Coots [Anastasia_Coots@cargill.com]; Bauer, Jeff [Bauer.Jeff@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]
CC: Robin Eichen-conn [Robin_Eichen-Conn@cargill.com]; Hanley, Mary [Hanley.Mary@epa.gov]; Bolen, Derrick [bolen.derrick@epa.gov]
Subject: RE: Request Suspend P-18-0101 for further review

Hi Anastasia,
I've heard you've now had a few calls with the program and hopefully we are moving towards a common understanding and good resolution.
Please let me know if you have further concerns.

Regards,
Nancy

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From: Anastasia Coots [mailto:Anastasia_Coots@cargill.com]
Sent: Wednesday, April 25, 2018 4:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Robin Eichen-conn <Robin_Eichen-Conn@cargill.com>
Subject: Request Suspend P-18-0101 for further review

Hello Jeff,

We will need to suspend the PMN for at least 15 days as we discussed in order to give us time to respond to the most recent information received from the risk assessment team. I will be out of office until May 7th but can still be reached by cell phone.

I received the fax of the risk assessors summary based on the changes to calculations and the addition of other data or endpoints since reviewing with Nancy more than three weeks ago. I did actually expect the reports or summary presented to Nancy to be included and the explanation to the changes. I had also expected some summary or additional detail on their determinations to why the assessors chose not to use the additional OECD 421/422, repeat tox data, and referenced material that we have provided for analogs of the ester. Will it be possible to get the additional determinations in writing for the reference data provided and why they are still choosing the LOEL for the fatty acid and not any of the toxicity data provided on the substantially similar esters?

For us, this is not about not wanting to require gloves through a SNUR. This is about the potential commercial impact of the additional regulatory burdens of a SNUR and the perceived health risk implied to this chemical versus others used in industry.

We need better guidance on what data and scientific evidence or references that can be provided that will elevate the concerns raised by the risk assessors. From our conversation, the indication that even if we did complete new OECD 421/422 with a positive outcome of a NOAEL of 1000 mg/kg/day or greater using our manufactured chemical would not

change the risk assessors concerns that are driving the recommendation for a SNUR is insufficient for us to be able to address how to move forward.

We will make a full response or would like to provide additional information if possible for review but also need better understanding of the additional references newly added by the risk assessor to support their concerns.

The second point of the summary, references a repeat tox dermal absorption study that was used as a secondary NOAEL for risk calculations by the assessors to support concerns. The study referenced has a LOEL of 2000 mg/kg/day (NOAEL of 800 mg/kg/day) and is included in the 2010 HPV Screening Assessment for the category of chemicals. This study has been used by EPA as a basis of risk determination for the chemical Category in the past "as not likely" for human health concerns. Based on that study, EPA made determination in 2010 that no further testing was necessary, however, the use in the risk calculation would seem to be a reversal of EPA's earlier findings for HPV chemical category. Is EPA reversing their previous determinations for the whole category under the HPV Assessment? There has been multiple subsequent 90-day repeat tox and OECD 421/422/414 oral reference data submitted that has been used as a weight of evidence for the category. It is unclear why it would now be used in risk calculations to support concerns?

We would like to also provide additional supporting information or data in regards to the third and last claims of the potential thermal degradation of the chemical made by the risk assessor in their summary, however, they did not provide any references to what they are basing their assumptions. Our knowledge and the additional industry standards which require testing under ISO, IEEE, UL certifications do not support the statements made by the risk assessors. We would like guidance on what information they are using as reference or data that we can provide that would be helpful to review to elevate this concern.

Thanks,

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